

Fed. Circ. Won't Revisit Restasis Patent Ruling

By **Andrew Westney**

Law360 (March 6, 2019, 7:21 PM EST) -- The Federal Circuit refused Wednesday to rethink a panel's ruling that Allergan and the St. Regis Mohawk Tribe's patents for the dry-eye drug Restasis are invalid, leaving in place a win for generic-drug makers planning to produce their own versions of the drug.

In a brief order Wednesday, Federal Circuit judges denied a December bid by Allergan PLC and the Mohawk tribe for panel rehearing or rehearing en banc of a circuit panel's November ruling, a move opposed by generic-drug companies Teva Pharmaceuticals USA Inc., Mylan Inc. and Akorn Inc., which are all developing generic versions of Restasis.

Counsel for the parties did not immediately respond to requests for comment Wednesday.

A three-judge panel on Nov. 13 affirmed a lower court decision that found claims in several Restasis patents invalid for obviousness.

In their petition for rehearing, Allergan and the tribe contended that the panel ruling was an unwarranted expansion of the so-called blocking patent doctrine, which generally does not allow a company to use commercial success as an indicator of nonobviousness if the company owns a patent that would block others from competing with it.

Allergan argued that the panel barred not only evidence of Restasis' commercial success but also evidence of a long-felt need for the dry-eye treatment, a decision that contradicted the appellate court's precedent by categorically applying the doctrine and failing to conduct a fact-specific analysis, the company said.

If left to stand, the panel's decision "threatens innovation and is problematic in any form," according to the December petition.

The generic-drug makers responded in February that the panel's one-line affirmance did not create a circuit precedent and did not address the "blocking patent" doctrine or any part of the district court's opinion, thus making rehearing of the case improper.

Instead, the affirmance "applied black-letter obviousness law to case-specific disputed questions of fact," the generic-drug companies said. "It is hard to imagine a more inappropriate candidate for rehearing en banc."

The patent claims relate to clinical research that found a greater benefit to patients from a lower concentration of Restasis' active ingredient, cyclosporine. Allergan had called that a "surprising clinical finding" that the district court failed to properly consider when deciding to invalidate the claims.

The generic companies had jointly pushed back on that argument, telling the Federal Circuit in January 2018 that Allergan's arguments about surprising results were based on "cherry-picked data points" and "statistical manipulation."

U.S. Circuit Judge William C. Bryson, who invalidated the patent claims after a trial in October 2017, had found that Allergan had "substantially overstated" improvements in effectiveness when comparing different cyclosporine formulations.

Allergan transferred the patents in question to the St. Regis Mohawk Tribe and licensed them back in an effort to stymie generic-drug rivals by seeking cover under tribal sovereign immunity. The Federal Circuit in July rejected that maneuver in a separate case that Allergan and the St. Regis Mohawk Tribe have since appealed to the U.S. Supreme Court.

In late February, Teva's closely watched challenge to the U.S. Food and Drug Administration's new policy on generic-drug exclusivity was ruled to be premature by a D.C. federal judge who found the company may have forfeited exclusivity under other policies.

U.S. District Judge Randolph D. Moss found that Teva lacked standing and tossed the drugmaker's October suit accusing the FDA of improperly denying the company 180-day exclusivity for a proposed generic version of Restasis

The patents-in-suit in the current case are U.S. Patent Numbers 8,629,111; 8,648,048; 8,685,930; and 9,248,191.

Allergan is represented by Jonathan E. Singer, Susan E. Morrison, Robert M. Oakes and Deanna J. Reichel of Fish & Richardson PC. The St. Regis Mohawk Tribe is represented by Michael W. Shore, Christopher L. Evans and Joseph F. DePumpo of Shore Chan DePumpo LLP.

Mylan is represented by Douglas H. Carsten, Wendy Devine and Christina E. Dashe of Wilson Sonsini Goodrich & Rosati PC.

Teva is represented by John C. Rozendaal, Michael E. Joffre, R. Wilson Powers III, Pauline M. Pelletier and William H. Milliken of Sterne Kessler Goldstein & Fox PLLC.

Akorn is represented by Michael R. Dzwonczyk, Mark Boland and Benjamin Cappel of Sughrue Mion PLLC.

The case is Allergan Inc. et al. v. Teva Pharmaceuticals USA Inc. et al., case number 18-01130, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Jeff Overley, Matthew Bultman and Tiffany Hu. Editing by Connor Relyea.